

Number: CMS-10388 (OMB#: 0938-NEW); Frequency: Once; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 6; Total Annual Hours: 270; (For policy questions regarding this collection contact Robin Preston at 410-786-3420. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage> or email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office at 410-786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by June 28, 2011:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 25, 2011.

**Martique Jones,**  
Director, Regulations Development Group,  
Division B, Office of Strategic Operations and  
Regulatory Affairs.

[FR Doc. 2011-10370 Filed 4-28-11; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10224]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the

Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Healthcare Common Procedure Coding System (HCPCS); *Use:* In October 2003, the Secretary of Health and Human Services delegated the Center for Medicare and Medicaid Services (CMS) authority to maintain and distribute HCPCS Level II Codes. As a result, the National Panel was delineated and CMS continued with the decision-making process under its current structure, the CMS HCPCS Workgroup (herein referred to as "the Workgroup"). CMS' HCPCS Workgroup is an internal workgroup comprised of representatives of the major components of CMS, and private insurers, as well as other consultants from pertinent Federal agencies. Currently the application intake is paper-based. However, the process has grown and the HCPCS staff is exploring electronic processes for the collection and storage of applications. We have received feedback on the nature of the application; and have streamlined the form into a user-friendly application. The content of the material is the same, but the questions have been refined in accordance with comments received from industry members; and the level of necessity of the information required to render quality coding decision as determined by the CMS workgroup. The information on the form is used to update the HCPCS code set. All information is received and distributed to CMS' HCPCS workgroup and is reviewed and discussed at workgroup meetings. In turn, CMS' HCPCS workgroup reaches a decision as to whether a change should be made to codes in the HCPCS code set. The respondent who submits the application form can be anyone who has

an interest in obtaining a code or modifying an existing code. However, respondents are usually manufacturers of products, or consultants on behalf of the manufacturer. *Form Number:* CMS-10224 (OMB#: 0938-1042); *Frequency:* Occasionally; *Affected Public:* Private sector, business and other for-profit and not-for-profit institutions; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 3300. (For policy questions regarding this collection contact Felicia Eggleston at 410-786-9287 or Lori Anderson at 410-786-6190. For all other issues call 410-786-1326.)

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on May 31, 2011.

OMB, Office of Information and  
Regulatory Affairs, Attention: CMS  
Desk Officer, Fax Number: (202) 395-  
6974, E-mail:  
[OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: April 25, 2011.

**Martique Jones,**  
Director, Regulations Development Group,  
Division B, Office of Strategic Operations and  
Regulatory Affairs.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0087]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; CONVENIA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for CONVENIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these Acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA approved for marketing the animal drug product CONVENIA (cefovecin sodium). CONVENIA is indicated for the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Pasteurella multocida* in cats; and the treatment of skin infections (secondary superficial pyoderma, abscesses and wounds) caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G) in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CONVENIA (U.S. Patent No. 6,020,329)

from Pfizer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 2, 2009, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of CONVENIA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CONVENIA is 2,841 days. Of this time, 2,801 days occurred during the testing phase of the regulatory review period, while 40 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the FD&C Act became effective:* July 17, 2000. The applicant claims November 16, 1999, as the date the investigational new animal drug application (INAD) became effective. However, the date that a major health or environmental effects test is begun or the date on which the Agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, is the effective date for the INAD. According to FDA records, July 17, 2000, is the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act:* March 17, 2008. The applicant claims March 15, 2008, as the date the new animal drug Application (NADA) for CONVENIA (NADA 141-285) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141-285 was March 17, 2008, which is considered to be the initially submitted date for NADA 141-285.

3. *The date the application was approved:* April 25, 2008. FDA has verified the applicant's claim that NADA 141-285 was approved on April 25, 2008. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,462 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets

Management (*see ADDRESSES*) either electronic or written comments and ask for a redetermination by June 28, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 26, 2011.

To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (*See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.*) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 2011.

**Jane A. Axelrad,**  
Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011-10379 Filed 4-28-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0381]

### Generic Drug User Fee; Public Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to provide a public update and to gather additional stakeholder input on the development of a generic drug user fee program. A user fee program could provide necessary supplemental funding, in addition to current Congressional appropriations, to facilitate the timely review of human generic drug applications by FDA, and FDA is currently in negotiations with the regulated industry aimed at providing a consensus proposal for congressional consideration. In the interest of transparency, and to assure that all interested stakeholders' views are heard and considered, whether they are present at the negotiations or not, FDA is holding a public meeting to